EXHIBIT E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

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IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	Master File No. 2:12-MD-02327
	:	MDL NO. 2327
DAWN BAKER, et al	:	
v.	:	CASE NO. 2:12-cv-02476
ETHICON, INC., et al.	:	

- - -

August 11, 2016

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Expert deposition of KONSTANTIN WALMSLEY, M.D., taken pursuant to notice, was held at Courtyard Marriott West Orange, 8 Rooney Circle, West Orange, New Jersey, beginning at 12:04 p.m., on the above date, before Kimberly A. Cahill, a Federally Approved Registered Merit Reporter and Notary Public.

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I N D E X

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KONSTANTIN WALMSLEY, M.D.,
after having been duly sworn, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MR. PRITCHETT:

Q. Would you tell us your name, please?

A. Konstantin Walmsley.

Q. And what is your professional address?

A. 777 Bloomfield Avenue, Glen Ridge, New Jersey 07028.

Q. Dr. Walmsley, my name is Chuck Pritchett. I represent Ethicon and Johnson & Johnson in this lawsuit brought by Dawn and Michael Baker.

Do you understand that you've been identified as a case-specific expert in this lawsuit by the Bakers?

A. Yes.

Q. And do you understand that

we are here today to talk about all of your specific -- case-specific opinions, the grounds and basis for those opinions?

A. Yes.

Q. And as you know, this is my only opportunity to talk to you, so if you could make sure to try to give me all of your opinions and the grounds for those opinions, I would appreciate it.

A. Certainly.

Q. And you're prepared to discuss all of your opinions and the basis for those opinions today?

A. Yes, sir.

Q. I understand you have four case-specific opinions: One, that Ms. Baker has scar plate formation due to the TVT Secur?

A. Yes.

Q. Two, that her complaints of pelvic pain and dyspareunia are caused by the scar plate formation?

A. Yes.

Q. And you performed a

differential diagnosis. Right?

A. I did.

Q. Your third opinion is that she still is experiencing pelvic pain, vaginal pain, dyspareunia, and mixed urinary incontinence?

A. Yes.

Q. And your last opinion addresses her prognosis.

A. That's correct.

Q. Any other opinions that I missed or are contained in your report?

A. No, I don't believe so.

Q. And of course I'm leaving out -- you have two general causation opinions as well; correct?

A. Yes, sir.

Q. And by the protocol, we're not here to talk about those today.

A. That's correct.

Q. Okay.

Can you tell me when you were first retained by Ms. Baker's legal counsel to do work in this case?

A. It would have been in the mid to latter part of May.

Q. May of this year?

A. That's correct.

Q. And you've worked with that law firm before?

A. I had.

Q. And when did you first begin your work for your opinions in this lawsuit?

A. At some point in June, I would have begun my work on this case.

Q. And that's about the time that you performed an independent medical examination of Ms. Baker?

A. Yes, sir.

MR. PRITCHETT: And this is not totally a memory test. I'll give you your report to refer to as we proceed.

I want to mark as Exhibit 1 to your deposition the deposition notice.

- - -

(Deposition Exhibit No. Walmsley (Baker)-1, Notice of Deposition of Konstantin Walmsley, M.D., was marked for identification.)

- - -

THE WITNESS: Thank you.

BY MR. PRITCHETT:

Q. Have you seen that notice before I just handed it to you?

A. I have.

Q. Schedule A requests that you bring certain documents described there. Can you tell me what, if anything, you brought with you today?

A. What I have today is my laptop computer, which has electronic versions of many of the Schedule A requests.

Q. Well, can you tell me what those are?

A. It has my curriculum vitae. It contains my reliance list. It would contain my report, and it also may

contain some of my billing, although I sometimes have billing on one of my other computers.

Q. Any other documents?

A. No.

Q. What about medical records?

MS. SANTRA: We're going to -- I will send you a link of all the medical records that were sent to Dr. Walmsley. And I have his C.V. and reliance list that were served with the report if you need those.

BY MR. PRITCHETT:

Q. Can you tell me approximately how much chargeable time has accrued for your work in this case?

A. Yes. Roughly 7 to 11 hours to the best of my recollection.

Q. And you charge $500 per hour; is that correct?

A. Yes, sir.

Q. Does that include deposition testimony?

A. Yes.

Q. Is that the same charge for performing an IME?

A. Not exactly. A lot of -- my IME charges tend to be vetted or scrubbed through the office, so I don't get compensated for the IME. My practice gets compensated for the IME.

Q. Do you charge $500 per hour for reviewing medical records?

A. Yes.

Q. And I was going to ask you, your work in this case, is this run through your practice group, which is Urology Group of New Jersey, or you individually?

A. Me individually.

Q. Is there anything requested in Schedule A which you did not -- well, you didn't bring anything, but which we've omitted?

You mentioned your report, your C.V., your reliance list, maybe some billing. Plaintiffs' counsel's going to

send me a link to medical records. Anything else?

A. No.

MR. PRITCHETT: I'm going to mark as Exhibit 2 your report.

- - -

(Deposition Exhibit No. Walmsley (Baker)-2, Rule 26 Expert Report of Konstantin Walmsley, M.D., was marked for identification.)

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MR. PRITCHETT: Counsel, do you have a copy of the report to refer to?

MS. SANTRA: Yes.

BY MR. PRITCHETT:

Q. Does that appear to be a copy of your report?

A. Yes.

MR. PRITCHETT: And I'm going to mark as Exhibit 3 your C.V. that was provided to us at the time your report was served.

- - -

(Deposition Exhibit No. Walmsley (Baker)-3, 11/20/15 Curriculum Vitae of Konstantin Walmsley, was marked for identification.)

- - -

BY MR. PRITCHETT:

Q. Does that appear to be a copy of your C.V.?

A. Yes, sir.

Q. There was some mention of an updated C.V. Can you tell me what would be updated?

A. The only thing I updated were some of my extracurricular, nonprofessional activities.

Q. Do any of those extracurricular activities have anything to do with your opinions in this case?

A. No, sir.

Q. Or your work in this case?

A. No.

Q. You said they're

nonprofessional?

A. Yes, sir.

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(Deposition Exhibit No. Walmsley (Baker)-4, Document Titled "Materials Reviewed", was marked for identification.)

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BY MR. PRITCHETT:

Q. I'm going to hand you what I've marked as Exhibit 4. That is your -- what you called the reliance list. And I believe on here, it's called "Materials Reviewed."

Is there anything to be supplemented for the reliance list?

A. No.

Q. Was the reliance list prepared by you or Ms. Baker's legal counsel?

A. It was prepared by me.

Q. And were there any materials that you considered for your opinions in this case that you requested, but did not

receive?

A. No.

Q. It mentions depositions of medical providers?

A. Correct.

Q. Is it your understanding that there were any depositions of medical providers in this case?

A. Not in this case, no.

Q. You mentioned instructions for use and on that you put Gynecare TVT instructions for use. Do you see that?

A. I do.

Q. Is that the IFU you reviewed for your opinions in this case?

MS. SANTRA: Object to the form.

THE WITNESS: Not specifically.

BY MR. PRITCHETT:

Q. Does that pertain to your general causation opinions?

A. The general causation opinions are related, yes, to the TVT

IFU, but it's applicable to the year in which the case relates to and also the type of TVT product, whether it's, for example, TVT Secur, which has a different IFU -- it's meant to encompass or incorporate all of them. If that's not specific there, I apologize.

Q. So you did review the TVT Secur IFU for your opinions in this case?

A. Yes.

Q. Did you actually read over the IFU again or just relying upon your past use of it?

A. I read it over again.

Q. And you mentioned the patient brochures as well?

A. Yes.

Q. Did you have any communications with Ms. Baker's treating doctors?

A. No, sir.

Q. Did you feel that that wasn't necessary for your opinions?

A. I felt that it wouldn't have

been very helpful, correct.

Q. Would you have liked to have had access to a deposition of, for instance, Dr. Hodges, who implanted the TVT Secur?

MS. SANTRA: Object to form.

THE WITNESS: I think the depositions of the implanting surgeons can in certain instances be helpful.

BY MR. PRITCHETT:

Q. How can they be helpful?

A. To perhaps give me an impression of, in a surgeon's words, the indications for the procedure, his or her understanding as to the risks, benefits, and alternatives at the time when they were providing informed consent and executing the procedure, and also to perhaps give additional information peri-procedurally as far as how patients did and their attributing benefits, complications, and such to the -- to -- you know, in their words, what the

patient was experiencing.

Q. Were you provided with any summaries of medical records prepared by others?

A. Not to my knowledge, no. I don't recall any.

Q. You didn't prepare any medical chronology or summaries?

A. My medical chronology was really generated on the report kind of as a realtime document as I was going through the records.

Q. Were you -- you mentioned that you had depositions -- well, let me take that back.

Did you review the deposition of Ms. Baker?

A. I did.

Q. I didn't see it listed on your reliance list.

A. If you look at my expert report -- and I apologize for the confusion -- at the bottom of page 2, her deposition was part of my review.

Q. Bottom of page 2 of your report.

A. Correct. The reliance list, if I was being more thorough, I would have probably written "Depositions of Medical Providers and/or Patient," which I did not, to my discredit.

Q. Did you review the deposition of her husband?

A. I don't recall seeing her husband's deposition.

Q. And, again, you didn't feel that that's necessary for your opinions and conclusions in this case?

A. I would say, perhaps not necessary, but could have been helpful.

Q. Have you communicated in any way with other experts in this case?

A. No.

Q. Plaintiffs have designated other expert witnesses, so you haven't talked to them?

A. Yeah, I mean, I don't know of all of them, so -- but I don't believe

so, no.

Q. Have you read any of the other expert reports?

A. I've read one expert report.

Q. Which one was that?

A. If you want to call it that. It was Dr. Khandwala's IME, Salil Khandwala.

Q. Sure. So you have a copy of his report?

A. Yes.

Q. Did you bring that today?

A. I have it here, yes.

Q. Have you exchanged or shared documents with any of the other experts in this case, regardless of whether you talked to them or not?

A. No.

Q. So you're not relying on the opinions of other experts in this case for your opinions.

MS. SANTRA: Object to form.

THE WITNESS: No, not -- not directly, I'm not.

BY MR. PRITCHETT:

Q. What do you mean by "directly"?

MS. SANTRA: Object to form. He's incorporated the TVT-S general opinions in his reliance list.

THE WITNESS: Yeah.

BY MR. PRITCHETT:

Q. So did you review -- you mentioned you did not review the reports of other experts in this case; correct?

A. I didn't know if you were speaking about case-specific or general reports, so I stand corrected. I thought you were talking about case-specific reports.

Q. That's fine and I should have clarified.

Did you read the general causation reports?

A. I've read some of them.

Q. For this case.

A. Correct.

Q. Which ones did you read?
A. In this instance, the Jerry Blaivas general report.
Q. Who I understand you know. Right?
A. He trained me a long time ago, yes, yeah.
Q. Any others?
A. Primarily just that one.
Q. Why did you read his report?
A. I -- well, I found it helpful. I found it comprehensive and, you know, I think of him as a key opinion leader in the world of pelvic reconstructive surgery, so I lend a lot of weight to his opinions.
Q. Did you read his report before you formulated your opinions in this case?
A. I had read it before then, I believe, yeah.
Q. Which of your specific causation opinions did you rely on Dr. Blaivas' report for?

MS. SANTRA: Object to form.
THE WITNESS: Specific opinions.
MR. PRITCHETT: Yes.
THE WITNESS: Well, I think, to be fair, I'd probably have to look at his report to specifically answer your question, but certainly as it relates to some of the complications this individual suffered, Dr. Blaivas describes in his causation reports the incidence of these complications and the fact that he sees them in patients implanted with mesh.
BY MR. PRITCHETT:
Q. So it deals mainly with complication rates of certain complaints patients have?
MS. SANTRA: Object to form.
THE WITNESS: Well, I think some of it's that and some of it also is qualitative as well as quantitative data.

MR. PRITCHETT: Let me hand you what I'm going to mark as Exhibit 5.

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(Deposition Exhibit No. Walmsley (Baker)-5, 6/20/16 Encounter Summary for Dawn Baker, was marked for identification.)

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MR. PRITCHETT: And this is what's called encounter summary, dated June 20, 2016.

I think these are your notes from your IME; is that correct?

THE WITNESS: That's correct.

MR. PRITCHETT: You may want to keep Exhibits 2 and 5 handy when we start talking about her specifically.

THE WITNESS: Okay.

BY MR. PRITCHETT:

Q. Are there any written materials concerning what you did for

your case-specific opinions and what you found in your examination of Ms. Baker other than what's in Exhibit 2, which is your report, and Exhibit 5, which is your encounter summary --

A. No.

Q. -- or the IME report?

A. Right. No, there's not.

Q. If you'd look at Exhibit 2, which is your report, look at the third page, under "Clinical History" --

A. Yes.

Q. -- you listed certain dates and treatments of Ms. Baker in the past; correct?

A. Yes.

Q. Why did you list those particular events rather than others?

A. Generally speaking, I tried to provide bullet points in the clinical history that were in my opinion reflective or contributory to the reasons for my report.

Q. Is that another way of

saying these were relevant to your report?

A. Yes.

Q. Is it fair to say that other records of visits to healthcare providers are not relevant to your report?

MS. SANTRA: Object to form.

THE WITNESS: I would probably say less relevant. I mean, there may be a finding in a visit of, I don't know, pelvic pain or something that one might consider as somewhat relevant, but to my estimation, perhaps not relevant enough to be provided in the summary.

BY MR. PRITCHETT:

Q. I notice that the last visit that's noted in "Clinical History" was June 30, 2009, which was her postop visit with Dr. Hodges; is that correct?

A. Yes.

Q. And, again, why wouldn't you want to look at records of her treatment

after the implant surgery?

A. Well, to some degree, I may not have had or may not have seen those records; and to the other extent, I guess I put forth the relevance.

Q. So are you saying you may not have all of her medical records?

MS. SANTRA: Object to form. Since this report was written, we have sent more records that we've gotten to Dr. Walmsley. So when he wrote this report, he may have had less records than he does today, if that makes sense.

MR. PRITCHETT: Is this link going to tell me what records he had before he prepared his report?

MS. SANTRA: Well, he tells you on page 2 --

MR. PRITCHETT: He lists providers.

MS. SANTRA: Yep, I can set it up that way.

MR. PRITCHETT: So, yeah, I

would like to know exactly what he had --

MS. SANTRA: Sure.

MR. PRITCHETT: -- at the time he finalized his report and then what was sent subsequently.

MS. SANTRA: Okay.

BY MR. PRITCHETT:

Q. Do you happen to know that, Dr. Walmsley?

A. It wasn't a lot of stuff that I received subsequently. I don't remember the specifics.

Q. Is it possible you had no medical records pertaining to Dawn Baker's care and treatment after the mesh surgery other than her postop visit?

A. I don't believe that to be the case.

Q. So were -- is it your understanding that plaintiffs' counsel were choosing which records for you to review?

MS. SANTRA: Object to form.

THE WITNESS: I don't think that's the case either, because -- I mean, that hasn't happened with previous work I've done for the lawyers who retain me for this case.

BY MR. PRITCHETT:

Q. When you undertook your work in this case, did you want to have her complete medical records pertaining to her care and treatment?

A. Of course, yeah.

Q. When you received what medical records you did before you prepared your report, did you think those were the complete records of her care and treatment?

A. That was my understanding.

MS. SANTRA: Object to form. I'll just state for the record, as discovery is ongoing, we get -- we receive more records for each case every day. So to the extent you're trying to imply we're

withholding records from Dr. Walmsley, that was not the case.

BY MR. PRITCHETT:

Q. Sitting here today -- strike that.

So you've received some additional medical records from plaintiffs' counsel that reflect visits with healthcare providers after her implant surgery; correct?

A. Yes.

Q. So you know she sought some care and treatment after implant surgery; correct?

A. Correct.

Q. Do -- since we -- well, do any of those postimplant medical records other than her postop visit have any significance to your opinions?

A. No.

Q. Looking at your materials relied upon again, let's go back to the instructions for use. You mentioned that you did look at the TVT Secur IFU;

correct?

A. Yes, I did.

Q. How often in your practice do you review instructions for use?

A. Often, yeah.

Q. What is "often"?

A. Well, if I'm doing a procedure over and over again, I don't look at the IFU each time for the procedure, but I always like to review it during the first few executions of a procedure, both before and even afterwards, just to corroborate, for example, my surgical technique.

And I would say, every six months to a year, I like to revisit the IFU, not only to refresh my memory, but just to kind of reinforce my understanding of a product when using it.

Q. Is that the only source of information you look at when you're using a product?

A. No.

Q. What other sources of

information do you look at?

A. Well, I think there are different things you try to glean from a product. I mean, as far as surgical technique, for example, some of that, I can derive from key opinion leaders, papers that describe procedure.

As far as expectations of the procedure, peri-procedurally, risks, benefits, some of that information can be extracted from authoritative textbooks, manifests that are peer reviewed or written by key opinion leaders.

There are workshops and cadaveric labs that device manufacturers also organize that can be helpful as well.

Q. You mentioned that you look at the IFU partially for risk information?

A. It helps me, yeah.

Q. Would it be within the standard of care for a surgeon to only look at the IFU for risk information

before using a product?

A. I would say so. I would think so.

Q. Do you think it's important for surgeons to look at articles and studies as well for risk information?

A. I think that can be helpful as well, yes.

Q. Don't you agree that the more a product is used, more information becomes available about benefits and risk information?

MS. SANTRA: Object to form.

THE WITNESS: Well, I think you're -- well, it depends upon the specific benefits or risks being put forth, but possibly, yes.

BY MR. PRITCHETT:

Q. So is it important for a surgeon such as yourself to keep abreast of that type of information as it becomes available?

A. I think that's helpful.

Q. And where do you get that information other than the IFU?

A. Well, I think the same things I put forth before in your question.

Q. So professional organizations.

A. To some extent, professional organizations. You know, more so updated literature, interactions with key opinion leaders, whether they come in the form of device manufacturer-organized conferences or other types of venues and conferences.

Q. Okay. And you do that in your practice?

A. I try to, yeah.

Q. You mentioned in your Exhibit 4 incorporated materials -- well, we already talked about that.

You mentioned the medical literature in your reliance list, which is Exhibit 4; correct?

A. Yes.

Q. Did you specifically look at

any of these -- any of this literature other than the IFU in preparing your report in the Dawn Baker case?

MS. SANTRA: Object to form.

THE WITNESS: Well, obviously, some, I relied upon more than others; but, you know, the reality is, I -- each article has a certain amount of weight in terms of allowing me to arrive at opinions.

Was there one particular article that was very, very helpful in me formulating my opinions on Dawn Baker? I mean, as we sit here today, I can't say, oh, well, I really found the Duckett article more helpful, for example. As we sit here today, I can't point to one or a number of articles that were more relied upon than others.

BY MR. PRITCHETT:

Q. Do these articles also

pertain to your general causation opinions?

A. Yes.

Q. Are you able to differentiate which of these articles pertain to your general causation opinions as opposed to your specific causation opinions?

A. Well, my two general opinion articles in the Dawn Baker case relate to proper informed consent and the fact that safer alternative designs were in existence.

So to that end, the AMA at 8.08, information relating to informed consent, the TVT Secur instructions for use are obviously very instrumental to my general opinions.

And then primarily towards page 3 of my reliance list, there is some data relating to autologous rectus fascial slings and their equivalents that specifically play into general opinion number 2.

So those are some of the references in my reliance list that were perhaps a little bit more impactful for my general opinions formulations.

Q. I didn't see on your reliance list any Ethicon documents other than the IFU and the patient brochure; is that correct?

MS. SANTRA: Object to form. He's -- we talked about the incorporated materials in the general TVT Secur report.

BY MR. PRITCHETT:

Q. What Ethicon documents other than the IFU and the patient brochures are you relying upon for your case-specific opinions?

MS. SANTRA: Object to form.

THE WITNESS: Really, primarily, those are the only ones that are Ethicon specific.

BY MR. PRITCHETT:

Q. What about depositions of Ethicon representatives; are you relying

upon any of those for your case-specific opinions?

A. We talked about Dr. Blaivas' report. Is that something that should be included in this or --

Q. No, I'm talking about depositions of representatives or individuals of Ethicon.

A. Pardon me. None.

Q. And can you tell me what you did to prepare for this deposition?

A. Yes. I briefly re-reviewed Dawn Baker's medical records, including the updated records I was provided. I re-reviewed my expert report and my IME report and I also re-reviewed the report of Dr. Khandwala.

Q. Do you know Dr. -- and I'm going to butcher his name -- Khandwala?

A. I do not.

Q. And of course you met with counsel; correct?

A. Briefly this morning, yes.

Q. We'll talk a little bit

about some of your background so I get a better understanding.

You are a board-certified urologist; correct?

A. Yes, sir.

Q. And in your practice, do you treat men and women?

A. I do.

Q. And what's the percentage breakdown between men and women?

A. It's about two-thirds and one-third, two-thirds men/one-third women.

Q. Has that changed in recent years or has that been the way for a while?

A. Been about the same for a while now.

Q. And "for a while," I mean, the last ten years or so?

A. Yeah, I think that's about right.

Q. And your practice includes treating women for SUI; correct?

A. Yes.
Q. And do you treat women for other urinary dysfunction?
A. Yes.
Q. Such as urge problems?
A. Yes.
Q. And you do -- does your treatment include nonsurgical treatment?
A. Yes.
Q. And it also includes surgical treatment; correct?
A. Yes.
Q. And can you tell me the types of surgery you use now to address SUI in women?
A. Yes. Urethral bulking procedures, autologous fascial sling treatments, and mid-urethral polypropylene mesh sling surgery.
Q. And the bulking, are they injections; is that how that works?
A. These are injections into the urethra, yes.
Q. Have your patients benefited

from mesh mid-urethral slings?

A. Most of them have.

MS. SANTRA: Object to form. This is getting into the general area that doesn't have a lot to do with Ms. Baker.

BY MR. PRITCHETT:

Q. Have you had good experience with them?

A. With what?

Q. Mesh mid-urethral slings?

A. Fairly good experience, yes.

Q. And you mentioned polypropylene. Is this the same polypropylene that you use in your practice that was used in the TVT Secur?

A. I'm not sure.

Q. Well, it's a polypropylene mesh; correct?

A. Yeah, but -- this is true.

Q. So --

A. In that sense, that's correct.

Q. Configuration may be

different?

A. You know, the edge of the TVT Secur mesh was palpably, to my examination, having felt multiple meshes, was different. It was a sharper-edged mesh, but it was a polypropylene lightweight mesh.

Q. You agree that TVT Secur is a lightweight, large-pore polypropylene mesh?

A. Yes.

Q. And all of the mesh slings that you currently use are large-pore polypropylene?

A. Lightweight mesh, yes.

Q. And I know from reading about you that your practice has changed a little bit on your surgical treatment. So tell me, how many polypropylene mid-urethral slings have you implanted in your career to treat SUI in women?

MS. SANTRA: Object to form.

THE WITNESS: I would reckon -- I mean, in the hundreds,

probably -- somewhere between 225 and 350 or in thereabouts.

I was a more active implanter earlier in my career. I'm less active of an implanter now, but I still do the procedures.

So I'm thinking to myself, if I've been in practice for 12 years and I was as busy as 20 to 30 a year, but then it tapered off to about maybe 10, it's somewhere in that 200-plus range of some kind.

BY MR. PRITCHETT:

Q. But you still use polypropylene mesh slings for treatment of SUI in women?

A. In select women, I do, yes.

Q. And when's the last time you used the mesh sling?

A. About three weeks ago.

Q. You mentioned that you also do autologous fascial sling procedures;

correct?

A. I do.

Q. How do you decide whether to use the autologous fascial sling in a patient versus the mesh mid-urethral sling?

A. Well, it's a joint discussion between the patient and myself. So some of the dynamic to use one or the other is patient driven and some of it is perhaps more doctor driven.

As far as the consideration I put in towards using autologous fascia as opposed to synthetic mesh, it depends on their degree of sexual activity and it also depends to some degree on their age and also to some degree on their understanding and willingness to accept mesh-specific risks.

Q. When you said it was patient driven, what did you mean by that? Are you talking about those factors?

A. I think, to some degree, I'd almost just as soon educate the patient

towards my concerns and what I think are pros and cons of each and then deferring the judgment to the patient.

Q. Are there advantages of synthetic mesh mid-urethral slings over autologous fascial sling procedures?

MS. SANTRA: Object to form.

THE WITNESS: To some degree.

BY MR. PRITCHETT:

Q. What are those?

A. Well, there's less morbidity because they're -- in the sense of incision, because if you're using an autologous fascial sling, you have to harvest this tissue from the host site.

For the surgeon, it takes a bit more time and sweat equity, if you will, to execute the procedure. So it's a little more laborious for the surgeon, which for a patient may be an advantage because it's a shorter procedure; for a surgeon, might be an advantage because the sling, quite frankly, is technically

an easier procedure.

Q. So it's, generally speaking, an easier procedure?

MS. SANTRA: Object to form.

MR. PRITCHETT: I'm talking about the mesh.

THE WITNESS: From a technical standpoint, the mesh is felt to be easier. I think that's a reasonable conclusion.

BY MR. PRITCHETT:

Q. And it's quicker?

MS. SANTRA: Object to form.

THE WITNESS: It's a quicker procedure.

BY MR. PRITCHETT:

Q. Is it outpatient?

A. Yes.

Q. Is autologous fascial sling procedures outpatient?

A. Usually that's a 23-hour admission, you know, where they'll stay overnight.

Q. From the extra incision, can

additional complications occur in the autologous fascial sling procedure?

MS. SANTRA: Object to form.

THE WITNESS: Those are infrequent, but they can happen.

BY MR. PRITCHETT:

Q. And what are those?

MS. SANTRA: Object to form.

THE WITNESS: Wound infections, pain at the incision site. There theoretically can be risks of hernias where the mesh is excised, although typically that doesn't really occur.

BY MR. PRITCHETT:

Q. Can that pain become chronic?

MS. SANTRA: Object to form.

THE WITNESS: I've never seen that myself, but I suppose in theory it can.

BY MR. PRITCHETT:

Q. Have you ever taken part in studies regarding the treatment of SUI in

women?

A. No.

Q. Have you published any peer-reviewed literature regarding mesh mid-urethral sling procedures?

A. I have not.

Q. Or the products themselves?

A. I have not.

Q. Have you taken part in studies regarding the treatment of SUI in women using autologous fascial slings?

MS. SANTRA: Object to form.

THE WITNESS: I have not.

BY MR. PRITCHETT:

Q. Have you ever used TVT products?

A. I have.

Q. And which ones did you use and approximately when?

A. I used the TVT Classic from 2001 to 2005. I used the TVT-O in the 2006 to 2007 arena. And that is it.

Q. Between 2001 and 2007, were you also performing autologous sling

procedures to treat SUI in women?

MS. SANTRA: Object to form.

THE WITNESS: Earlier on, yes.

BY MR. PRITCHETT:

Q. What do you mean, "earlier on"?

A. You pointed to a six-year window --

Q. Yes -- here's my point: At the time you were using TVT products, you were also in some cases doing autologous fascial sling procedures --

A. That's correct.

Q. And how would you -- again, would you use the same process to decide for a patient which procedure to use?

A. Well, it's different today than it was back then.

Q. How is it different?

A. Well, today, my concerns as it relate to the permanence of some of the complications I've seen with mesh slings, there is a higher proportion of

patients who would, let's say, more strongly consider the autologous fascial sling than the mid-urethral sling procedure.

And for that matter, there's a growing number of patients in my practice that would just as soon defer on surgery altogether rather than getting the problem fixed.

Q. Just live with it.

A. There's more patients who have taken on that opinion.

Q. But when you were using the TVT products between 2001 and 2007, what would drive you to recommend to a patient using autologous fascial slings?

A. Well, I think to be fair, you're talking about a span of time where I was a resident, a fellow, and then in private practice.

So obviously, as a resident and fellow, I didn't have as much input into the choice of procedure being done. In my private practice, I really only

used TVT on the order of a handful of times before I started using other products anyway, and I really wasn't doing many autologous fascial slings early in my private practice because there had been such a full swing or shift towards the use of the mid-urethral slings at that time.

Q. But when you did use it, what would drive that consideration, autologous fascial slings versus a TVT product?

A. Primarily the attending that I was working with at the time, because when I first got into private practice, I wasn't performing any autologous fascial slings. I was using exclusively mid-urethral slings.

Q. During 2001 to 2007, were you using mesh mid-urethral slings manufactured by others?

A. Yes.

Q. And what types did you use?

A. I used the AMS SPARC kit. I

used the Boston Scientific kit, which I believe was called Obtryx at the time, and then I also started using a sling made by Bard called the Uretex sling.

Q. And what would drive you on which manufacturer's sling to use?

MS. SANTRA: I'm going to object to form that this is all general opinion. We've gone almost an hour now without talking about Ms. Baker.

THE WITNESS: Those decisions were a little bit more kind of subjective. They weren't necessarily based on my -- an objective conclusion that one mesh was different or better than the other.

In the instance of my early years, I probably used the Bard sling because I appreciated the elasticity to that sling and felt -- as it felt ex-vivo, without having been implanted, it felt

more smooth and supple.

BY MR. PRITCHETT:

Q. I'm going to get into some of the potential risks of mesh surgery and we'll get into as it relates to Ms. Baker as well, but you agree that mesh mid-urethral surgery to treat SUI in women has -- it is a pelvic floor surgery; correct?

A. Yes.

Q. And there are certain potential risks of pelvic floor surgery whether using mesh or not using mesh; correct?

A. Correct.

Q. And dyspareunia is a risk of pelvic floor surgery; correct?

MS. SANTRA: Object to form.

THE WITNESS: Yes.

BY MR. PRITCHETT:

Q. Scarring is a risk; correct?

A. Correct.

Q. Voiding dysfunction's a risk.

A. Correct.

Q. Potential for surgery in the future to address problems is a risk.

MS. SANTRA: Object to form.

THE WITNESS: Well, that's a little bit of apples to oranges. I mean, I think generally speaking, that's true; but obviously, as we know, the use of mesh creates additional surgeries that are more mesh specific, if you will.

BY MR. PRITCHETT:

Q. But whether you're using mesh or not, there could be complications that arise that would require additional surgery; correct?

MS. SANTRA: Object to form.

THE WITNESS: In theory, true.

BY MR. PRITCHETT:

Q. Have you known of an instance where additional surgery was needed to address a problem arising from

a pelvic floor surgery that did not use mesh?

A. Yeah. Yes.

Q. Has that happened to you or to someone -- one of your colleagues?

A. That has happened to one of my colleagues as a matter of fact.

Q. And just to move on, would you agree that bleeding, wound complications, adhesions, nerve damage, neuromuscular problems, and fistula formation are all potential risk of pelvic floor surgery?

A. Yes.

Q. And would you agree that those potential risks were discussed in medical literature by the time of Ms. Baker's surgery in June of 2009?

A. I would believe so.

Q. Would you agree that those are all potential risks of TVT Secur surgery as well; correct?

A. Yes.

Q. And the risks that we just

went through, you yourself learned those from colleagues, studies, reading articles that we talked -- talked about before; is that correct?

MS. SANTRA: Object to form.

THE WITNESS: And my own personal clinical experience, yes.

MR. PRITCHETT: And your own clinical experience.

BY MR. PRITCHETT:

Q. Is any one source of information about potential risks more important than the other?

MS. SANTRA: Object to form.

THE WITNESS: I mean, I guess there could be more importance as it relates to reliability or credibility of the source.

You know, for example, if, you know, a colleague of mine at a community hospital said, oh, I experienced complications A, B, and C with this, but they didn't

give me the severity, the true incidence, I would probably weight that less than what, for example, is put forth in an IFU or, for example, what a key opinion leader might share with me in the context of a peer-reviewed article, so...

BY MR. PRITCHETT:

Q. All right.

It's fair to say, since we don't have the deposition of Dr. Hodges and you've never talked to her, we don't know what she discussed with Ms. Baker in June of 2009 preceding her TVT Secur surgery; correct?

A. That's correct.

Q. And you can't say what Dr. Hodges knew about the potential risks before performing the TVT Secur surgery on Ms. Baker; correct?

MS. SANTRA: Object to form.

THE WITNESS: Correct.

BY MR. PRITCHETT:

Q. Is it your experience then

that doctors armed with information about potential risks and complications decide what to talk to the patient about; correct?

A. I believe that's what happens, yeah.

Q. Is it your experience that some doctors are more thorough and detailed in their discussions with patients about potential risks and the informed consent process than others?

MS. SANTRA: Object to form.

THE WITNESS: I would imagine that exists.

BY MR. PRITCHETT:

Q. Are you critical in any way of Dr. Hodges' recommendation to use the TVT Secur for Ms. Baker?

A. I'm not.

Q. I take it you read the operative report?

A. I did.

Q. And all of Dr. Hodges' records preop and postop?

A. Yes, I have.
Q. Any criticisms of her technique in the surgery?
A. No.
Q. Any criticisms of her care and treatment before or after the surgery?
A. No.
Q. Do you know -- let me back up.
Can the TVT Secur be implanted using a U approach or a hammock approach?
A. Yes.
Q. Do you know which approach Dr. Hodges used?
A. I'd have to look again at that operative note to recall.
Q. Is that significant to your opinions, which approach she may have used?
A. Yes, and I recall the approach she used, but I don't have her operative note in front of me to relate

to that. I'd have to really see it to specifically recall it.

MR. PRITCHETT: Let me see if I can find it for you.

We can, if you want, make this an exhibit, but I'm just more concerned about refreshing his memory.

Let me hand you what is titled "Operative Report, Western Baptist Hospital, June 18, 2009" for Dawn Baker.

(Pause.)

THE WITNESS: So I suspect that it was a -- a hammock or transobturator placement.

BY MR. PRITCHETT:

Q. And why is that significant to your case-specific opinions?

A. Well, sometimes in the setting of pelvic pain, especially if patients have groin pain, it's more consistent with the transobturator approach as opposed to the retropubic

approach.

Q. Thank you.

A. You're welcome.

Q. Do you know what training Dr. Hodges received for mesh mid-urethral sling procedures before Ms. Baker's surgery?

A. I'm not aware of that.

Q. Of course you don't know what medical literature she may have read before Ms. Baker's surgery in 2009?

A. No, sir.

Q. You don't know what her clinical experience was with TVT Secur with her patients?

A. I do not.

Q. Do you have any basis for thinking that the IFU for the TVT Secur was the only source of information available to Dr. Hodges to assess potential risks and complications before recommending Ms. Baker's surgery?

A. I do not.

Q. Do you know -- you don't

know if she even read the IFU for the TVT Secur before Ms. Baker's surgery; correct?

A. I don't know the answer to that question.

Q. Well, you don't know if she had ever read it before Ms. Baker's surgery; correct?

MS. SANTRA: Object to form.

THE WITNESS: Yeah, I don't know if she did or did not read it, that's correct.

BY MR. PRITCHETT:

Q. Now, you've never designed a mesh product. Right?

A. I have not.

Q. Have you ever designed any kind of medical device?

A. No, not directly.

Q. What do you mean by "not directly"?

A. I mean, I've never gotten a patent for modifying or changing a device, but I've come up with, you know,

creative ways in the operating room to make devices work more effectively for me. They're off label and not patented.

Q. Well, I don't want to coopt your innovations and run to the patent --

A. It's quite all right. I'm happy to share it with you --

Q. -- and run to the patent office.

A. Yeah. But I can give you examples of where I've jerry-rigged, you know, devices to make them work better for me, if that's -- but that doesn't answer your question.

Q. But never commercialized.

A. No, sir.

Q. Have you ever consulted with a manufacturer about information to be included in an IFU?

A. I've not.

Q. And you don't consider yourself to be an expert in FDA medical device labeling requirements?

A. No.

Q. Do you consider yourself an expert in any way on the laws and regulations of the Food and Drug Administration?

A. I do not.

Q. Is it your opinion that -- or do you have an opinion one way or another whether Dawn Baker had ISU in June of 2009 before her surgery?

A. SUI, do you mean?

MR. PRITCHETT: SUI. What did I say?

MS. SANTRA: ISU. I thought it was a term I hadn't heard before.

MR. PRITCHETT: Let me try that again.

BY MR. PRITCHETT:

Q. Do you have an opinion whether Ms. Baker had SIU (sic) -- I almost did it again -- in June 2009 before her surgery?

A. Yes.

Q. And what is that opinion?

A. When she saw Dr. Hodges in May of 2009, she had complaints consistent with SUI.

Q. You mentioned that, in your -- you had read some of the medical records pertaining to Dawn Baker prior to her treatment by Dr. Hodges; correct?

A. Yes.

Q. Do you agree that Ms. Baker had mixed urinary incontinence before her mesh sling surgery?

A. In part, I do, yes.

Q. What part do you not agree with?

A. The urodynamic testing that was done on June 17th was more reflective and documented as SUI; however, she did have overactive bladder complaints and had been on overactive bladder drugs prior to that time.

So I think the records support the presence of mixed urinary incontinence, although there's some mention made to stress urinary

incontinence more so than mixed.

Q. And you're relying on the -- Dr. Hodges' records to say that she had SUI predominantly over urge?

A. Yes. Both Dr. Hodges and her primary care doctor, too, for that matter.

Q. Do you know -- and we'll look at some records.

Do you recall how long Ms. Baker had mixed urinary incontinence before her mesh sling surgery?

A. Roughly three years or so.

MR. PRITCHETT: Let me hand you what I'm marking as Exhibit 6.

- - -

(Deposition Exhibit No. Walmsley (Baker)-6, Notes of Office Visits from Rural Health for Dawn Baker, BAKERD RURALH_MDR00024, was marked for identification.)

- - -

BY MR. PRITCHETT:

Q. And, Doctor, I'll represent to you that these are medical records we obtained from Rural Health pertaining to the care and treatment of Dawn Baker. I want to -- at least these are notes of office visits; does that look like that's what Exhibit 6 is?

Do you agree that these are office notes from a visit, it appears; correct?

A. Yes.

Q. The date was cut off on the top, but I'll represent to you that the date on the top office visit is August 9, 2006 and you can see a transcription date on the bottom, 8/29/06.

Do you see that?

A. I do.

Q. I just want to go over the symptoms that she was seeing someone for. It says: She is complaining of urinary stress incontinence. When she has to get to the bathroom, she has to go then or she won't make it.

Did I read that correctly?

A. Yes.

Q. Does that sound like SUI or urge or something else?

A. It sounds more urge consistent than SUI consistent.

Q. And if you'll look at the next visit on the same exhibit, it appears to be an office visit July 10, 2007. Do you see that?

A. Yes.

Q. And the symptoms states: Patient presents today with complaints of urinary incontinence and bladder spasms. She wants something done.

A. Yes.

Q. She has to take a change of clothes. She leaks if she laughs, coughs, or sneezes. She has difficulty if she has to urinate. If she does not get to the bathroom right away, then it is too late.

Did I read that part correctly?

A. Yes.
Q. And does that sound like mixed incontinence?
A. It sounds more like mixed incontinence in this description, yes.
Q. Can you tell from that description which one is predominant over the other?
A. It's hard to.
MR. PRITCHETT: Let me hand you what I'll mark as Exhibit 7 --
THE WITNESS: Can we take a break?
MR. PRITCHETT: Sure.
(A recess was taken from 1:12 p.m. to 1:17 p.m.)
BY MR. PRITCHETT:
Q. Are you ready to continue, Doctor?
A. Yes, sir.
- - -
(Deposition Exhibit No. Walmsley (Baker)-7, Notes of Office Visits from Rural Health

for Dawn Baker from January and February 2009, was marked for identification.)

- - -

BY MR. PRITCHETT:

Q. I'm going to hand you what's been marked as Exhibit 7. And these are additional office visits from Rural Health in 2009, before Ms. Baker's surgery in June.

I want you to look at the office visit of February 10, 2009. Do you see that?

A. Yes.

MS. SANTRA: Can I have a copy?

MR. PRITCHETT: Oh, I'm sorry. I'm just holding it.

MS. SANTRA: Thank you.

BY MR. PRITCHETT:

Q. It states: She wants to talk to me and discuss the Depo. She is having some breast tenderness. She said she started having vaginal bleeding

today. She has been having pain after intercourse that will last for 10 to 15 minutes just in the last couple of weeks.

Did I read that correctly?

A. Yes, sir.

Q. Do you interpret the Depo to refer to Depo-Provera?

A. Yes.

Q. And that's a female hormone contraceptive; correct?

A. Correct.

Q. Are you familiar with that drug?

A. Somewhat, yeah.

Q. Is pain after intercourse a side effect of that drug?

A. I'm not sure.

Q. Does this indicate to you that she was having painful intercourse before her mesh surgery?

A. Not to my mind, no.

Q. Why is that?

A. Only because she's not having pain with intercourse. It's pain

after intercourse. And I think, from a technical standpoint, I mean, dyspareunia is pain with intercourse.

Q. Okay.

A. Yeah.

MR. PRITCHETT: Let me hand you what I'm marking as Exhibit 8.

- - -

(Deposition Exhibit No. Walmsley (Baker)-8, 5/11/09 Notes of Date of Encounter with Dawn Baker by Kupper, BAKERD_UGP_MDR00002 through BAKERD_UGP_MDR00007, was marked for identification.)

- - -

BY MR. PRITCHETT:

Q. And this is notes from a -- records from a Dr. Robert Kupper who is a urologist in Paducah. And it's dated May 11, 2009.

Did you review this record before formulating your opinions in this case or do you know?

A. I don't specifically recall this record.

Q. I want you to look at, under the history of present -- well, chief complaint is keeps wetting on self. Do you see that?

A. I do.

Q. And it's in quotes. And "History of Present Illness," I want to read a few sentences -- and please feel free to read the whole thing if you want, Doctor -- it says: Miss Baker is a 37-year-old Caucasian female sent to me in consultation by Dr. Tom Staton because of urinary incontinence. This lady has had trouble with wetting on herself for a year and a half, maybe a little bit longer. Over the past six months, however, it has gotten worse. She leaks when she cannot get to the bathroom in time. She gives me a history of what sounds like typical overactive bladder symptoms, frequency - voiding small amounts, urgency, cannot get to the

bathroom and will leak on her way to the bathroom, or urge incontinence.

Did I read that mostly correctly?

A. Yes.

Q. And then it goes on to say she also leaks with coughing, laughing, sneezing.

And then he goes on to say that he -- he says it sounds like a combination or complex urinary incontinence; is that correct?

A. Yes.

Q. Do you agree just based upon that description that Ms. Baker before her mesh surgery had complex urinary incontinence?

A. Yes.

Q. And is that another way of saying mixed incontinence?

A. Yes.

Q. And you agree she had overactive bladder symptoms?

A. Correct.

Q. Can you tell from that record whether Ms. Baker had predominantly urge or frequency incontinence as opposed to stress at that time?

A. Could you repeat the question?

Q. I think I should.

You say in your report that you think she now has -- the urge incontinence predominates over stress.

A. I say that today?

Q. I think so -- well, or do you?

If you look at the next to the last page of your report, just above case specific opinion number 4 and you say, "Mrs. Baker currently has this complaint having evolved from a patient with an SUI-dominant incontinence picture to a predominantly urgency urinary incontinence form of MUI."

A. That's correct.

Q. Do you think, based upon the

urologist in Paducah, that Ms. Baker, a month before her mesh implant surgery, had predominantly urgency urinary incontinence?

MS. SANTRA: Object to form.

THE WITNESS: I do not think so, no.

BY MR. PRITCHETT:

Q. Why is that?

A. Well, I think, to his words, first off, it's complex and, second off, his history of the present illness as well as his physical examination really points towards a true mixed component.

She has history of stress incontinence. She also has a history of urge incontinence. She has physical exam findings of urethral hypermobility consistent with stress incontinence, but wouldn't allow one to conclude that it's entirely stress incontinence.

She's been given medications that would theoretically help with overactive bladder or urgency-related

incontinence, but those medications have proven to be ineffective. In other words, I think it's truly mixed.

Q. Do those medication -- you're referring to Detrol or Enablex?

A. Correct.

Q. Do they also cure urinary urge incontinence?

A. They occasionally can cure urge incontinence. The most typical scenario is that they have some degree of positive impact on that.

Q. But they don't always work.

A. They don't always work, but oftentimes in the setting of true urgency incontinence from overactive bladder, you'll see at least some dent or impact on the problem, not that you would always see that, but typically you do.

Q. I guess I don't understand -- other than the medication part, medication's not working -- why you can conclude that at this point in time that she had a -- SUI predominated over urge.

A. A lot of that comes from the urodynamics report that Dr. Hodges performed.

Q. But based upon this record, putting aside -- we'll get to Dr. Hodges.

A. Okay.

MS. SANTRA: Object to form.

THE WITNESS: Based on this record, I think it would be more challenging as a standalone record to opine that one type of incontinence predominates over the other.

BY MR. PRITCHETT:

Q. Any significance to you that he could not elicit any stress incontinence at the examination?

A. Not especially, no.

Q. And then his plan on the next page talks about going slow, trying a nonoperative approach, which includes dietary changes, Kegel exercises, not -- timed voiding, et cetera.

Do you agree with his plan?

A. I think it's reasonable.

Q. And how long would it take to determine whether the nonoperative approach was working?

A. I would imagine at least a couple of weeks.

MR. PRITCHETT: Let me hand you Exhibit 9, I think which will be the last new exhibit.

- - -

(Deposition Exhibit No. Walmsley (Baker)-9, 6/18/09 "Appendix B - Bladder Health Questionnaire (Sample)" for Dawn Baker, BAKERD_PSR_00007 and BAKERD_PSR_00008, was marked for identification.)

- - -

BY MR. PRITCHETT:

Q. And this is a bladder health questionnaire dated June 18, 2009. This was out of Dr. Hodges' office.

Is this a record that you looked at before formulating your

opinions in this case?

A. Yes.

Q. And is this, a bladder questionnaire, something you use in your practice?

A. Not this type of questionnaire directly, but certainly similar questions are asked.

Q. And this is self-reporting by the patient, you think?

A. Yes.

Q. Do you -- in looking at this, particularly where it says -- the question's about, "Do you lose urine when," can you tell from this whether Ms. Baker had urge predominating over stress or vice versa?

A. No.

Q. And look at the third question from the bottom. It says, "Have you ever had urethra (bladder tube) stretched?" And she marked "yes."

A. Yes.

Q. Do you know what that's

referring to?

A. As a child, she had a urethral dilation procedure performed.

Q. And what is that?

A. A urethral dilation procedure is a procedure where the urethral tube is serially stretched open or dilated, usually with the use of metal rods that are called sounds.

Q. Sounds terrible.

A. Probably better to do under sedation, yes.

Q. Can that cause any lasting problems with urinary dysfunction?

A. Well, it depends on if the problem re-presents itself, in other words, urethral stenosis or urethral stricture.

I get the sense that with her, the problem didn't return because she's never been treated for that condition since that time.

Q. You can put that aside.

I want to talk to you about

your IME, and you examined her in your New Jersey office; is that correct?

A. Yes.

Q. And you've performed exams for litigation before?

A. I have.

Q. And when you're retained as an expert for litigation, do you always do an exam before giving your opinions?

A. Not always.

Q. So you've given opinions in litigation without an examination.

A. I have.

Q. And what determines whether you do an examination of a litigant or not?

A. I don't know if I can completely answer that question because sometimes I'm not even asked to.

Q. Okay. Well, that may be the answer. Sometimes you're asked to, sometimes you're not; correct?

A. I think that might be one of the answers, yeah.

Q. Did she have any -- did she report any difficulties traveling to New Jersey?

MS. SANTRA: Object to form.

THE WITNESS: I don't quite recall.

BY MR. PRITCHETT:

Q. Sitting here, if she walked in the door, would you recognize her?

A. I would.

Q. Because that was just a few months ago?

A. Yeah, it was June 20th specifically.

Q. Did anyone accompany her to your office?

A. I don't specifically recall that.

Q. Was anyone present in the room for the exam?

A. Yes.

Q. Who?

A. One of my medical assistants.

Q. Did she bring any documents with her, like medical records or anything else?

A. No.

Q. What did you know about Ms. Baker before you did your examination in June?

A. Not very much. I typically try to review medical records after the IME, only because I find that I can see and meet the patient and have a clearer, kind of unfettered conscience, if you will, about the patient.

Q. Had you reviewed any medical records at all?

A. I may have, but more often than not, I typically review the medical records after the IME.

Q. Had you read her plaintiff fact sheet or any of the other materials that had been sent to you?

A. That, I did not look at beforehand.

Q. Did counsel request any

facts or data that they wanted you to consider in your exam?

A. No.

Q. And was that the only meeting you had with her, Ms. Baker?

A. Yes, that was the only meeting.

Q. You've had no communications with her since.

A. I have not.

Q. And this was for purposes of an independent examination, but not for care and treatment; correct?

A. Yes.

Q. Any differences in how you would conduct an exam in your -- from your clinical practice?

A. No.

Q. What were the components of the exam?

A. History taking, followed by a physical examination, followed by a review of all the data and the designation of diagnoses or assessments.

Q. And how long did the actual examination last?

A. Probably about 45 minutes.

Q. And the rest was how long? How long was she with you total?

A. She was in the office probably for a good hour. I guess in terms of the physical exam portion of the evaluation, that was probably on the order of five to ten minutes.

Q. So you did a pelvic exam. Right?

A. Yes.

Q. Did you do testing of any kind?

A. Other than her urine analysis, no.

Q. So you didn't do a Q-Tip test or -- that's considered -- I consider that a test. Okay? So let's just make sure we got our terminology right.

Other than a pelvic examination, urinalysis, you didn't do

anything else.

A. Well, I did an examination outside of the pelvis as well.

Q. Sure.

A. But as it relates to the pelvis exam, I did not do a Q-Tip test. I did not perform a cystoscopy or a urodynamics test.

Q. Are the entire details of your exam described in your -- either your report, Exhibit 2, or your encounter summary, which is Exhibit 5?

A. Yes.

Q. Was she on any medications at the time? I think you indicate no medications reported, looking at Exhibit 5, first page in the middle?

A. Yeah. For whatever reason, there are no medications listed that she was taking.

Q. Was she wearing any pads or liners?

A. I did not see them on her when I examined her.

Q. Did you ask whether she was using pads or liners?

A. I did.

Q. What did she say?

A. She stated to me that she used pads for social reasons.

Q. Did she say when she -- I understand why she may wear them, but how often or --

A. She wasn't using them all the time or on a daily basis. The extent of my questioning was when she used them, and the answer that she gave me was, she used them for social reasons, but I didn't delve into the nature of her social reasons.

I concluded that it was probably if she was out for long periods of time or going to a party or going to the mall for a few hours, those types of instances. That was like my conclusion based on her answer.

Q. Did she tell you anything about her urethral stretching?

A. Not specifically.

Q. Can you tell me your objective findings of the presence of SUI during that visit?

A. Well, I didn't specifically tailor my exam to generate objective findings of SUI, because if I were to have done that, I would have, for example, had her do some provocative maneuvers with her bladder full.

By the time she had seen me, she had submitted a urine analysis and for the most part had emptied her bladder. So examining patients in that fashion, you're not going to elicit objectively stress incontinence because their bladder has no fluid in it.

Q. I understand.

If her bladder had been full, would you expect her to leak if she stood and coughed?

A. I would expect her to be at risk for that, yes.

Q. Okay.

A. Yeah.

Q. What do you mean by "at risk"? She may or may not?

A. Well, I mean, I think, strictly speaking, different patients have different leak point pressures. If she was someone who had mild stress incontinence, she might not necessarily leak reproducibly with a provocative maneuver as if she had severe stress incontinence, let's say.

Q. Could you determine whether she has mild or severe SUI?

A. I would probably term it in the mild to moderate category based upon her history, based upon what she was relating to me as the type and nature of her incontinence.

Q. Do you have an opinion whether her SUI is worse, the same, or not as severe as she had before her surgery?

A. I think it's hard to draw that conclusion. I wasn't able to glean

from her if it was worse and, if so, how. I mean, to some degree, one tries to do that on the basis of pad use or even pad weight. I'm not privy to that information, so it's hard to, quantitatively at least, point to severity before and after.

Q. Recurrence of SUI, though, was a known risk of mesh surgery at the time she had hers; correct?

A. Yes.

Q. Because not all the surgeries are a hundred percent successful; correct?

A. Right.

Q. You mentioned she also had urge incontinence?

A. Yes.

Q. How did you determine objectively whether she had urge incontinence?

A. Once again, you know, I think objective is a challenge. Because when I'm thinking objective findings, I'm

thinking, you know, active leaking onto a pad, having a feeling of urgency. So this was a largely clinical diagnosis made as much on history taking as it was on a physical exam.

Q. And she had urge incontinence before her mesh surgery, too. Remember us talking about that?

A. We did.

Q. Could you tell or can you tell me whether her urge incontinence is worse today, the same, or not as severe as -- than it was before the surgery?

MS. SANTRA: Object to form.

THE WITNESS: In terms of my interviewing of the patient, what I would conclude is that her mixed urinary incontinence today is now more urge today than it was stress.

So the question of, is her urgency urinary incontinence worse today than the urgency urinary incontinence she had before her

surgery is difficult for me to answer, because once again, we're talking quantitatively about the severity of her incontinence and I can't sit here and say she's using more pads today than she was, for example, before her surgery.

BY MR. PRITCHETT:

Q. And maybe this is asking the same question, just a little bit differently, but she had mixed urinary incontinence before her mesh surgery; correct?

A. Yes.

Q. And she has it now in your opinion; correct?

A. Yes.

Q. And would you give the same answer if I asked you whether her mixed incontinence is worse than it was before the surgery?

A. I think you have to just restate it again if you don't mind. I'm sorry.

Q. I asked you whether her SUI was different now than before her surgery.

A. Right.

Q. And I asked you about her urge, whether that was different now than it was before her surgery.

What about the overall package, the mixed incontinence; can you tell me whether in your opinion it's worse, the same, or not as severe as it was before her mesh surgery?

MS. SANTRA: Object to form.

THE WITNESS: I would probably only like to use the word different.

BY MR. PRITCHETT:

Q. How so?

A. Because I think, now, it's more urgency related than stress related, to her accounts at least.

MR. PRITCHETT: Can we take a short break?

(A recess was taken from

1:43 p.m. to 1:47 p.m.)

BY MR. PRITCHETT:

Q. Doctor, during your examination of Ms. Baker, did you see any evidence of exposure, erosion, or extrusion?

A. No, sir.

Q. Did you see any evidence of roping, banding, or curling?

A. No, I did not.

Q. Did you see any evidence of degradation?

A. No.

Q. What about contraction or shrinkage?

A. Yes.

Q. And what evidence did you observe?

A. Well, during my IME, there was some scar tissue noted underneath the sling.

Q. So you're looking at page 2 of Exhibit 5 under "Female Genitalia"?

A. That's correct.

Q. And is it the bold part, "Sling is palpable in the mid-urethra"?
A. Yes.
Q. "Mild induration noted laterally at the sulci"?
A. That's correct.
Q. More right than left?
A. Yes.
Q. And so is that the scar plate that you referred to in your report?
A. That's correct.
Q. You're inferring there's contraction or shrinkage because of the scarring that you felt; is that what you're saying?
MS. SANTRA: Object to form.
THE WITNESS: That's correct.
BY MR. PRITCHETT:
Q. And what causes the scarring?
A. Typically what happens when mesh is implanted is, there is a chronic

inflammatory response that generates fibrosis and scarring.

Q. Would you agree that the only way to know for sure if there was chronic inflammation is to do a biopsy?

A. I think that would be very helpful.

Q. Did you see any inflammation or redness in and around the urethra area?

A. I did not.

Q. Did you see redness or inflammation anywhere else?

A. I did not.

Q. I want to make sure I have all of Ms. Baker's symptomatic conditions which you are attributing to the mesh. You have pelvic pain. Right?

A. Yes.

Q. Vaginal pain. Right?

A. Yes.

Q. Now, is that only with intercourse where she has the vaginal pain?

A. Yes.
Q. So if she's not having intercourse, she's not having vaginal pain; is that correct?
A. Correct.
Q. And then you report mixed urinary incontinence, which we've talked about; correct?
A. Yes.
Q. Are there any other symptomatic conditions which you attribute to the mesh other than what we just discussed or just listed?
A. Just those three.
Q. You have no opinions about difficulties with bowel movements?
A. I do not.
Q. You have no opinions about numbness in her right leg?
A. I do not.
Q. You have no opinions about bleeding?
A. I do not.
Q. You have no opinions about

urinary tract infections?

A. Not directly, no.

Q. Well, what do you mean "directly"?

A. Well, sometimes one can see a higher risk of infections in patients who have voiding dysfunction and, as an example, patients with more severe incontinence can be at risk for urinary tract infections, patients who don't empty their bladders completely might be at more risk for urinary tract infections.

We've discussed that, quantitatively, it's hard for me to objectify if her incontinence is worse today than before her sling, so I can't directly correlate her urinary tract infection risk directly at least with the sling.

But if, in fact, her incontinence is an issue and her incontinence were to be worse, it would be something to consider.

Q. Do you agree that she had a history of urinary tract infections before the mesh sling surgery?

A. I do agree with that, yeah.

Q. And her uranalysis was normal?

A. That's correct.

Q. And you did not do a urine culture; correct?

A. I did not.

Q. And I didn't see urinary tract infection mentioned anywhere in your encounter summary, Exhibit 5, or Exhibit 2. Is it mentioned anywhere?

A. This is true.

Q. And you have no opinions about her claim to emotional injuries; correct?

A. No.

Q. I want to talk about the scar plate formation opinion a little bit. You agree that some scarring is expected in a mesh sling surgery; correct?

A. Correct.

Q. You mentioned the sling is palpable and I think you clarified it for me already. That was the -- you weren't palpating the actual sling. You were palpating what you thought was scar tissue; correct?

A. A little bit of both. I mean, I was palpating the scar tissue, but knowing that there was mesh material in and around it.

Q. But you couldn't feel the mesh.

A. I couldn't literally feel the actual mesh itself, no.

Q. Was the sling where you would expect it to be?

A. Yes.

Q. It didn't appear to have migrated or anything?

A. No.

Q. Did you detect and record any evidence of tenderness under the sling at the level of the mid-urethra

going to the periurethral space?

A. Periurethrally, yes.

Generally speaking, when I'm mentioning induration and pain reproducible on palpation, it's correlating with the induration that's noted. In her case, it was more so on the right side than the left side.

Q. And can you quantify, length or whatever, how much scar plate tissue you felt?

A. Well, I think to be fair, there was scar throughout the entire sling, but there was more thickness towards the edges.

So as you're extending out from the mid-urethra towards the periurethral tissues in the upper corners of the vagina, there was more scar tissue in those areas.

Q. Did she mention anything to you about feeling a tugging on her left side?

A. She developed feeling a

pulling pain on the groin on the right side.

Q. What about the left side? I didn't see it either.

A. She did not mention that to me.

Q. And let's go on to the -- because I have limited time. Let's go on to the -- your second opinion about the pelvic pain and dyspareunia.

Let me ask you first, where did you detect the pelvic pain?

A. So on physical exam, her pain was in the vaginal space, in the area of the sling, more so on the right lateral side of the sling than the left.

Q. And pelvic pain, again, was a known potential risk of any pelvic floor surgery; correct?

A. Yes.

Q. Can painful bladder syndrome cause pelvic pain?

A. Yes, it can.

Q. Do you think she has painful

bladder syndrome?

A. No, I don't.

Q. Why?

A. Well, she doesn't meet the criteria to have that syndrome.

Q. Okay. What is the criteria?

A. So interstitial cystitis or painful bladder syndrome is a disease state characterized by pelvic pain, accompanied by irritative voiding symptoms that typically has been going on for a period of time greater than six months.

The other diagnostic criteria include cystoscopy with findings that would otherwise be reflective of interstitial cystitis, usually findings whereby one sees changes within the bladder lining during the cystoscopy that would otherwise be reflective of interstitial cystitis.

In most instances, we're not encountering patients with interstitial cystitis. They're having frequency on

the order of 15, 20, 30 times, so they have fairly severe frequency.

Q. But the -- the severity of it can vary from 15 to 30. Right?

A. True.

Q. Can painful bladder syndrome cause dyspareunia?

MS. SANTRA: Object to form.

THE WITNESS: Possibly, yes.

BY MR. PRITCHETT:

Q. Was interstitial cystitis something that you considered in your differential diagnosis? Because I don't see it mentioned.

A. Yes.

Q. Where was it mentioned?

A. Well, recognized causes of dyspareunia following synthetic mesh sling surgery include a variety of different causations; and in my report, I list infection and inflammation, including, but not limited to, vestibulitis.

I rule that out on the basis

of the fact that not only did my exam not reflect that, but she had no at least recent history of interstitial cystitis in her medical records.

So based on my IME and the medical records that I reviewed in this particular setting, interstitial cystitis was not a factor I took into -- I mean, I -- I excluded it, shall we say.

Q. Did you recall seeing a medical record from her treating doctor, Dr. Cardenas, where he was considering the possibility of IC?

A. I do, yeah. Yes. Although, I think, to be fair, I thought Dr. Cardenas may have called to question possibly it being a bowel-related issue.

Q. And you don't think she has any bowel-related issues?

A. I don't recall any strong or compelling history of IBS or bowel issues in this patient.

Q. Did you -- I'm going to talk about the vaginal pain/dyspareunia. Did

you detect or note in your report or your encounter summary any tenderness in the vaginal opening?

A. Well, the tenderness was fairly close to the vaginal opening that I elicited, but it wasn't -- it didn't -- to your question, I didn't elicit tenderness immediately upon introducing my fingertips into Ms. Baker's vagina during the exam.

Q. It was with further penetration that you elicited --

A. Some.

Q. -- some tenderness?

A. Some -- some further penetration. I mean, perhaps between 1 and 3 inches upon entry.

Q. If there was -- she had tenderness in the vaginal opening, not 1 to more inches, but at the vaginal opening, would you agree that that could not be caused by the mesh?

MS. SANTRA: Object to form.

THE WITNESS: If it was

exclusively right at the introitus, it would be very hard to attribute that to pelvic mesh.

BY MR. PRITCHETT:

Q. You read Dr. Khandwala's report; correct?

A. I did.

Q. And he mentioned vulvodynia; correct?

A. There is mention made of that.

Q. Do you agree with his statements about vulvodynia?

A. When you say do I agree with it, I mean, it's memorialized as such.

Q. I don't understand.

A. I -- you know, I examined her vulva as well and I did not use a Q-Tip. I used my own gloved fingers and didn't get a similar response vis-a-vis pain.

But obviously he memorialized and documented not only did she have vulvodynia, but significant

vulvodynia.

Q. I'm going to jump down to -- because I'm running out of time -- to prognosis. And I just have a question. You say -- and this is opinion number 4, Exhibit 2 -- you say, in part, "Moreover, she has pelvic tenderness and residual scar tissue in the area where her mesh erosion was treated."

Is that a mistake?

A. That should not say that.

Q. It's the third sentence on your case specific opinion number 4.

A. No, that's incorrect.

Q. Is that left over from another report or --

A. That must have been some sort of a residual or not cutting a sentence out or something of that degree. That can be entirely omitted.

Q. You mention that future surgery could help address Ms. Baker's dyspareunia; correct?

A. Correct.

Q. Have any of her treating doctors ever recommended removal of the mesh sling?

A. Well, there's only one doctor in particular and Dr. Cardenas did not.

Q. Are you aware of any of her treating doctors who agree with you and say that the mesh is causing her symptoms?

MS. SANTRA: Object to form.

THE WITNESS: No.

BY MR. PRITCHETT:

Q. If she had not had surgery to treat her SUI in 2009, would she still likely have complex urinary incontinence that Dr. Kupper described?

A. I mean, assuming she had no other type of antiincontinence surgery whatsoever?

Q. Yes, sir.

A. I would imagine she would or she may.

Q. So she'd still have problems

wetting herself. Right?

MS. SANTRA: Object to form.

THE WITNESS: Likely.

BY MR. PRITCHETT:

Q. Is there any significance to you that Ms. Baker did not report to any healthcare provider any leaking until August of 2013, other than her postop follow-up visit with Dr. Hodges?

A. To one extent, based on her specifically, the significance to me falls into the fact that she wasn't one to necessarily see doctors. She was somewhat of a stoic patient who really oftentimes didn't seek out medical care.

And I do recall with her in particular a bit of a disconcerting comment that she didn't see Dr. Hodges -- or she had trouble seeing doctors in the area because they weren't comfortable addressing what she perceived as a mesh-specific problem.

Q. Is that something she told you?

A. I recall her saying something to that extent to me and I found it a little disconcerting.

Q. Was that something she told you or something she said in her deposition?

A. Both.

Q. But she did see treaters between June of 2009 and August of 2013; correct?

A. She did.

Q. Any significance to you that she did not report painful intercourse to any treater following her 2009 surgery?

MS. SANTRA: Object to form.

THE WITNESS: What was the latter point? Was that 2013 that you said that, from 2009 to 2013?

MR. PRITCHETT: Well, on dyspareunia. Let me just ask it again.

BY MR. PRITCHETT:

Q. Any significance to you that Ms. Baker did not report painful

intercourse to any treater after her 2009 surgery?

MS. SANTRA: Object to the form.

THE WITNESS: I mean, the only significance I guess to that is, I guess, number 1, it depends on the context, if it's actually, number one, asked; and number two, to what extent she would be comfortable discussing that topic with a provider.

Obviously, the flip-side of that significance is that, well, maybe it wasn't as significant for her to bring it up, but I think there are obviously two sides of an analysis there.

BY MR. PRITCHETT:

Q. Any significance to you that Dr. Cardenas noted that Ms. Baker was menopausal in 2015?

A. Yes.

Q. What's the significance of

that?

A. Well, I think the significance of that is that when one enters their menopause, they do run the risk of things such as vulvovaginal atrophy, which could present problems with pelvic pain and/or dyspareunia.

Q. Is she to your knowledge under any hormone replacement treatment?

A. No, not to my knowledge.

Q. But you still rule out vaginal atrophy as a potential cause of her dyspareunia even though she is experiencing menopause?

A. Well, both during my IME and Dr. Khandwala's IME and even Dr. Cardenas' evaluation, there's no documentation of vulvovaginal atrophy.

Q. Tell me about any comments or criticisms you have of Dr. Cardenas' report that you said you reviewed.

A. You know, the only comments I would have are that he and I did our exams somewhat differently and probably

memorialized different findings. He also arrived at a conclusion that I wouldn't necessarily have arrived at, that being the diagnosis of interstitial cystitis.

Q. He also doesn't think she has recurrent SUI; is that correct?

A. He did put forth that opinion.

Q. Well, specifically, any criticism of how he conducted the examination? You said he did it differently.

A. Not per se. I mean, the only area of interest that I have just difficulty understanding is how the anterior fornix exam was described.

Q. And what's your difficulty in understanding that?

A. Well, he documents tenderness at the level of the bladder on bimanual exam. He and I have somewhat of a similar finding there as it relates to I find tenderness palpating the mesh at the vaginal sulci, which are quite near

the bladder.

And then there's another mention of tenderness at the level of the bladder just with a speculum exam, opening the anterior blade of the speculum, and I guess I don't understand where that tenderness is occurring.

In other words, is it occurring where the speculum is in contact with the vaginal tissues? Is it occurring where there's some pulling of scar tissue that's not near the speculum?

So just from a semantics standpoint, I'm not sure if the tenderness that Dr. Khandwala is describing in his physical exam is the same as mine.

Q. Okay.

A. The other critique obviously is, the idea of doing a cystoscopy is not an appropriate one. The patient did have on dipstick trace blood, which raises the possibility of microhematuria, and she did have irritative voiding symptoms.

That being said, the fact that once he got to 300 cc's, she had extreme discomfort, the fact that the bladder still looked completely normal at that time, in other words, had no inflammatory changes, leads me to have a hard time concluding that she must have had interstitial cystitis simply because there was discomfort with the cystoscope in her bladder at 300 cc's.

Q. Is it your opinion there's just no way that Ms. Baker has IC?

A. I would probably discount it on the basis of my own findings, but I think it's important to understand that interstitial cystitis, for lack of a better term, is a bit of a wastebasket diagnosis. It's not necessarily a diagnostic criterion where there are objective measures that need to be hit or obtained to make the diagnosis.

So it's a diagnosis that's certainly put forth on plenty of occasions, but a lot of times, the

footing or the objective criteria to support that diagnosis are challenging to put forth.

And I disagree with the diagnosis of interstitial cystitis, not only on the basis of my interview with the patient and my experience in treating the disease state, but also on the means by which the diagnosis was reached, on the basis of a cystoscopy where at 300 cc's, there was pain, but no changes in the bladder that would otherwise suggest inflammation, glomerulations, ulcers, or other findings that we see in patients with interstitial cystitis.

Q. Any other criticisms or areas of disagreement?

MS. SANTRA: Can we check on the time?

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(A discussion off the record occurred.)

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MR. PRITCHETT: Can I get

that one --

MS. SANTRA: Yeah, you can -- that's fine, actually.

THE WITNESS: The only other critique I would make is that Dr. Khandwala concluded that she had deep dyspareunia on the basis of his exam when, in fact, the pain that she had, which was at the level of the bladder, really is not necessarily one of deep dyspareunia.

It's actually dyspareunia that, location-wise, is more in the midportion or the distal portion of the vagina.

MR. PRITCHETT: Dr. Walmsley, thank you very much. I am out of time.

THE WITNESS: Thank you.

- - -

EXAMINATION

- - -

BY MS. SANTRA:

Q. I'm going to try to get right into it, because I know you need to go, but I may skip around a little bit.

I'm going to talk for a little bit about your reliance list. And when you wrote your report for Ms. Baker, you had reviewed Dr. Blaivas' general report on the TVT Secur; is that right?

A. I did.

Q. And you actually -- through your materials reviewed list, you incorporated Dr. Blaivas' general opinions on the TVT-S into your report; correct?

A. Yes.

Q. And in addition to Dr. Blaivas' general report on the TVT-S, you also note in general that the TVT-S can cause the types of symptoms that Ms. Baker has experienced; is that correct?

A. Yes.

Q. And you know that not only from Dr. Blaivas' report, but also from your clinical experience, your education

and training, and your review of the medical literature; correct?

A. Yes.

Q. And the medical literature that you listed in your reliance list, that's not an exhaustive list of every article you've ever read relating to polypropylene mesh; is that correct?

A. That's correct.

Q. And so, you know, these articles that you've listed, while they may be very relevant to Ms. -- your report for Ms. Baker, that's by no means an exclusive list of everything you've ever read; correct?

MR. PRITCHETT: Objection; form.

THE WITNESS: Correct.

BY MS. SANTRA:

Q. And so when you're rendering your opinions for Ms. Baker, you're relying on your knowledge from the time you were in medical school and all of those classes that you took and articles

that you've reviewed over the past, let's say, 15, 20 years; is that right?

A. Correct.

Q. And so that knowledge is somewhat cumulative; is that correct?

A. Yes.

Q. And so I think you stated earlier, it's kind of hard to point to one article versus another article. And is that because you're relying kind of on your general knowledge based on your experience and training just as a urologist for the past 15, 20 years?

A. That's in part true, yes.

Q. And I want to go to your opinion -- your first opinion in your report, your general opinion on the IFU for the TVT Secur in 2009. And what is your experience with IFUs?

A. I use IFUs in my practice to understand surgical technique and also understand potential precautions, adverse events, contraindications to the use of a device.

MR. PRITCHETT: Let me just object to questions about his two general opinions as opposed to his case-specific opinions. I was not permitted to ask about the general opinions and you should not be either.

MS. SANTRA: I've let you go on for probably over an hour about his general opinions. I simply objected. So I'm going to keep asking my questions.

MR. PRITCHETT: It was background, nothing about his general opinions.

MS. SANTRA: Okay. Well, I'm going to ask these background -- actually, I'm going to ask these questions about his opinion which is in his case-specific report for Ms. Baker, which you were allowed to go into in depth.

BY MS. SANTRA:

Q. And so in making your

opinion about the IFU for the TVT Secur in 2009, were you relying on your experience as a practicing urologist who reads IFUs regularly as part of your practice?

MR. PRITCHETT: Objection; form.

THE WITNESS: Yes.

BY MS. SANTRA:

Q. And who relies on those IFUs regularly when using medical devices?

MR. PRITCHETT: Objection; form.

THE WITNESS: Yes.

BY MS. SANTRA:

Q. And counsel asked you some questions about whether you can know what Dr. Hodges knew. Do you remember those questions?

A. Yes.

Q. And first off, you understand that Dr. Hodges has not been deposed yet in this case; is that correct?

A. Correct.

Q. And so to the extent you can't answer anything about -- any questions about Dr. Hodges' testimony, that's because -- that's not because you didn't read the deposition. That's simply because she hasn't been deposed yet; correct?

A. That's right.

Q. And does it matter to your general opinion number 1 -- would that change your opinion at all if Dr. Hodges never read the IFU?

MR. PRITCHETT: Objection to the form.

THE WITNESS: No.

BY MS. SANTRA:

Q. And why is that?

A. I think we talked about informed consent not relying solely upon the IFU. There are some clinicians that I think use the IFU more than others.

To my mind, I think when a clinician's not reading the IFU, he or

she to some opinion is still making an informed consent on the basis of the IFU, because the key opinion leaders that are writing the manuscripts, the other material that a clinician uses to gain informed consent probably as a touchstone is affected by the IFU to some degree.

Q. And you were asked some questions about whether all pelvic surgeries have risks. Do you remember those questions?

A. I do.

Q. Do the nature and characteristics of the complications for mesh versus nonmesh surgery, are those different?

A. Yes.

Q. And how are those different?

A. Well, insofar as mesh is a foreign body, it induces a different type of reactional response in host tissues; and as a result of the means by which the body reacts to mesh, typically, the inflammation, the healing process is

different. The inflammation is of a more chronic nature. The scarring is different when one uses mesh as opposed to biologic graft materials or even host materials.

As a result, you know, the qualitative nature of potential risks is greater and different.

Q. And so would listing the risks that go along with any surgery or any nonmesh pelvic surgery, would that be enough to warn about the nature and characteristics of the risks for a product like the TVT Secur?

MR. PRITCHETT: Objection; form.

THE WITNESS: No.

BY MS. SANTRA:

Q. And that's just because the, you know, listing vaginal pain doesn't really describe the differences that you've just talked about, for example?

A. That's correct.

Q. On your examination of Ms.

Baker -- strike that.

You talked earlier about your -- your opinion that there is evidence in Ms. Baker's case that she has had chronic inflammation with her TVT Secur; is that correct?

A. Yes.

Q. And how do you know that?

A. That's in large part based on my physical examination of Mrs. Baker that identified indurated tissue and even some tenderness in the area of her sling.

Typically, inflammation, that process generates scar tissue and can generate tenderness if it's still in play; in other words, if it's latent but active, the inflammation can generate tenderness.

So based on her exam, which not only demonstrates the scar plate, but the tenderness, I arrived at that conclusion.

Q. And does the absence of redness that you could see on an exam,

does that change your opinion at all about chronic inflammation?

A. No.

Q. And why not?

A. Because one doesn't need to necessarily appreciate a change in color to render that diagnosis. It can be made on different bases.

Q. And then with the scar plate that you felt upon examining Mrs. Baker, I think you said you couldn't feel the TVT Secur mesh itself; is that right?

A. I could not directly feel it. I mean, in large part, if it's not eroding or extruding, it's hard to really feel it, unless it's very, very thin with regards to the vaginal epithelium or lining that you're feeling it under.

Q. Even though you didn't feel the -- directly the TVT Secur mesh itself, you know that the TVT Secur is what caused that scar plate; is that right?

A. It's part of the scar plate,

yeah. It's really incorporated into that plate.

Q. Okay.

A. Yeah.

Q. And you know that based on its location or how do you know that?

A. Based on the description of Dr. Hodges on doing the surgery, based on my understanding of the surgery and the anatomy, it was very clear that where that scar plate was palpated was where the TVT Secur was placed.

The other thing also, just to make mention, that the TVT Secur has some wings at the end of the actual device, so it also serves as a means, if there's thicker scar tissue, generally where those wings are located can correlate with that.

Q. And did that -- was that the case with Ms. Baker?

A. To some degree, yes. She had somewhat more induration noted laterally where those wings would have

been.

Q. And how do you know that there was shrinkage or contracture in Ms. Baker's case?

A. So in Ms. Baker's case, I did not put forth the opinion that the mesh sling contracted. I mean, it might have contracted.

With single-incision systems, it's a little more difficult to make that conclusion in the absence of histology, because, in a lot of instances, if there is true mesh contraction, you'll actually feel the sling and feel some tautness or tightness to the sling.

In this instance, the contraction to my conclusion was more on the basis of wound contraction.

Q. Okay. So that was the scarring in the scar plate that you felt?

A. Correct, yeah.

Q. And on exam, you were able to reproduce her pain and specifically

Ms. Baker was tender at the vaginal sulci; is that correct?

A. Yes.

MR. PRITCHETT: Object to the form.

BY MS. SANTRA:

Q. And could painful bladder syndrome or interstitial -- or strike that.

Did painful bladder system or interstitial cystitis cause that tenderness that you felt at the vaginal sulci for Ms. Baker?

MR. PRITCHETT: Objection to form.

THE WITNESS: No.

BY MS. SANTRA:

Q. And did vulvodynia cause that tenderness that you felt at the vaginal sulci for Ms. Baker?

A. No.

Q. And the cause -- a cause for that would have been the TVT Secur device; correct?

A. Yes.

Q. And did you perform a differential diagnosis when coming to your opinions about Ms. Baker?

A. I did.

Q. And have you based your opinions concerning Ms. Baker on your clinical experience, your review of her records, your independent medical examination of Ms. Baker, and your knowledge of the medical literature?

A. Yes.

Q. When you performed your differential diagnosis for Ms. Baker, did you take into account her past surgical history, including a tubal ligation, cervical cancer with hysterectomy, and a urethra, I guess, stretching as a child?

A. Yes.

Q. And taking into consideration all of those past procedures, you found that the TVT Secur was a cause for her pelvic pain and dyspareunia; correct?

A. Yes.
Q. And you interviewed Ms. Baker; correct?
A. I did.
Q. Did she tell you about the nature of the pain that she feels when she attempts sexual intercourse -- when she has attempted sexual intercourse?
A. Yes.
Q. And do you generally believe her about that pain that she says she experiences?
MR. PRITCHETT: Objection to form.
THE WITNESS: Yes.
BY MS. SANTRA:
Q. And would your findings upon exam comport with her symptoms of that pain?
A. Yes.
Q. And Ms. Baker reported having some stress urinary leakage today; is that right?
A. Yes.

MR. PRITCHETT: Objection to the form.

THE WITNESS: Yes.

BY MS. SANTRA:

Q. And so -- and is the TVT Secur or was the TVT Secur sold by Ethicon as a permanent solution to stress urinary incontinence?

MR. PRITCHETT: Objection to the form.

THE WITNESS: I don't recall specifically permanent.

BY MS. SANTRA:

Q. Was the TVT Secur supposed -- intended to be a permanent device?

A. That's true, yes.

Q. And despite the TVT Secur being implanted, Ms. Baker continues to have stress urinary incontinence; correct?

MR. PRITCHETT: Objection to form.

THE WITNESS: Yes.

BY MS. SANTRA:

Q. Have you rendered all your opinions today to a reasonable degree of medical certainty?

A. I have.

MS. SANTRA: I think that's all I have for you. Thank you, Doctor.

THE WITNESS: You're welcome.

(Witness excused.)

(Deposition concluded at approximately 2:39 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, KONSTANTIN WALMSLEY, M.D., have the opportunity to read and sign the deposition transcript.

KIMBERLY A. CAHILL, a
Federally Approved Registered
Merit Reporter and Notary Public
Dated: August 16, 2016

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A

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PAGE	LINE	CHANGE

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 142, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

KONSTANTIN WALMSLEY, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____

Notary Public

LAWYER'S NOTES

PAGE	LINE	